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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,295	06/01/2006	Sudhir Paul	64229-2150	3691
20311 LUCAS & ME	7590 10/14/201 ERCANTI, LLP	1	EXAM	INER
475 PARK AVENUE SOUTH			PENG, BO	
15TH FLOOR NEW YORK,			ART UNIT PAPER NUMBER	
			1648	
			NOTIFICATION DATE	DELIVERY MODE
			10/14/2011	ELECTRONIC .

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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info@lmiplaw.com

Application No.	Applicant(s)	
10/581,295	PAUL, SUDHIR	
Examiner	Art Unit	
BO PENG	1648	

BO PENO BO	Office Action Summary		Examiner	Art Unit				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address − Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. If NO period for reply is apposited used the provided and of 27 GP1 1.13(id.), in no event, however, may a reply be finely filled If NO period for reply is apposited above, the maximum statistic protect will apply and will explay and well explore SIX (in) MONTHS from the mailing date of this communication. Fallule to prove within the set or centred period for reply will, by statisc, cause the application to become APAROMOED (36 U.S.C.) § 13(3). Any only received by the A cities inter than these moretic after the mailing date of this communication, even it simily filled, may reduce any evener place that ma agustrema. Set 97 CPR 1.70(db). Status 1) □ Responsive to communication(s) filled on 23 June 2011. 2b) □ This action is FINAL. 2b) □ This action is non-final. 3) □ An election was made by the applicant in response to a restriction requirement set forth during the interview on								
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Application/Control Number: 10/581,295

Art Unit: 1648

DETAILED ACTION

1. This Office action is in response to Applicant's reply filed on September 2, 2011.

Claims 51-65 are pending and are considered in this Office action.

Claim Rejections - 35 USC 112, first paragraph-Written description

2. The following is a quotation of the first paragraph of 35 USC 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

 (Prior rejection-maintained) The rejection of Claims 51-65 under 35 USC 112, first paragraph, for failing to comply with written description requirement, is maintained for the reason of record.

In response to Applicant's argument:

- 4. Applicant argues that the law establishes that a general allegation of unpredictability in the art is not a sufficient reason to support a rejection for lack of adequate written description. Hyatt v. Dudas, 492 F.3d 1365, 1370, 83 USPQ2d 1373, 1376 (Fed. Cir.2007). Applicant asserts that it is irrelevant what the definition of antibody is or that one of ordinary skilled in the art could not know what specific diseases the claimed antibody or fragment thereof treats. Because the reaction antigen/antibody is specific and selective, once the sequences of the light and heavy chain variable domains are known, a person skilled in the art is be capable of extrapolating the correspondent antigenic sequences without undue experimentation and with reasonable expectation of success. Most importantly, the presently claimed subject matter is not directed to a method of treatment of a specific disease, but rather is directed to specific antibodies which are well described and supported by the specification.
- 5. Applicant's argument is not persuasive for following reasons: Applicant appears to argue that the claimed invention is enabling. However, the rejection is made under 35 USC 112. first paragraph, because the claimed invention lacks written description. The

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claims describe the claimed antibody only by fragments of SEQ ID NO: 43, 44 or 46. The claims have failed to indicate which specific antigen the claimed antibody or fragments would interact. However, based on the definition of an antibody, an antibody is defined by its specificity of reacting to antigen, not by amino acid fragments. Without adequate description of the specificity, one of ordinary skill in the art cannot envision what is the claimed antibody or fragment thereof.

- 6. Moreover, the description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") In the present case, the claims lack adequate description of "a pharmaceutical composition" comprising fragments of SEQ ID NO: 43, 44 or 46. The specification has not shown that the claimed antibody or fragment can be used for treating any specific diseases or viral infections, providing clinical benefit. Given that a lack of indication of the specificity of the claimed antibody fragment, one of ordinary skill in the art cannot envision what specific diseases the claimed antibody fragment is canable of treating.
- 7. Accordingly, it is deemed that the specification fails to provide adequate written description for the claimed antibody fragments and pharmaceutical composition. Since Applicant's argument has failed to indicate the antigen of the claimed antibody fragment, it is not sufficient to overcome the rejection. The rejection is therefore maintained.

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Remarks

 No claims are allowed. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on Tu-F, 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/BO PENG/ Primary Examiner, Art Unit 1648